

Program - 2006 ORI Research Conference on Research Integrity
Friday December 1 - Sunday December 3, 2006
Conference information: http://www.cme.hsc.usf.edu/research_integrity/

Friday 1:30-3:30

Plenary: Trends, Challenges and New Research Areas

William Gardner The Social Cost of Scientific Misconduct and Questionable Research Practices

It is difficult to measure the prevalence of misconduct and questionable research practices (QRP), and harder to determine their social impacts. Current discussions focus on the direct costs of known misconduct cases. I present an initial economic theory of the indirect social costs of misconduct and QRP in medical research.

Carol R. Thrush Use of a Novel Content Analysis Method to Examine Trends in Research Integrity Literature

A pertinent indicator of significant and continued maturation of the field of research integrity is the increasing scholarly literature about research ethics and responsible conduct of research. This study uses a novel content analysis method to explore trends in the emergent field of research integrity literature over the past decade

Jill Rosenbaum Applying Dillman's Tailored Design Method to internet surveys.

Low response rates are a significant threat to the validity of population surveys. Self-selection biases can only be minimized by low refusal rates. Obtaining high return rates is, therefore, essential to the integrity and generalizability of survey based research. This paper will discuss problems and strengths of using Dillman's Tailored Design Method in conjunction with the web-based survey site, SurveyMonkey. We conducted a ORI funded study surveying research integrity with a better than 75 percent response rate.

Gwen W. Anderson Clinical Trial Registries in Gene Therapy Research: Do they Foster Access to Research and Public Trust?

This presentation reports Phase I of an ethnographic study aimed at describing the day-to-day operations and decisions that bear on conducting gene therapy clinical trials and regulatory paper work. Gaining access to active, gene therapy clinical trials in three regions of the U.S via Principal Investigators (PI) or Industry Sponsors has proven to be very difficult.

Friday 3:45-5:45

Plenary: Teaching and Behavior

Dena Plemmons Goals Reported by Instructors for Teaching of Research Ethics

The effectiveness of research ethics (responsible conduct of research, RCR) training is not yet well understood, in part because we are not clear about the goals or objectives for that training. The purpose of this study was to characterize the range of goals identified by RCR instructors.

Kenneth Pimple The Influence of Opportunity on Research Misconduct

Efforts to support research integrity and discourage research misconduct can benefit from the successes of OPPORTUNITY THEORIES of crime and deviant behavior which have been shown in real-world initiatives to reduce crime and police misconduct. We explain the fundamentals of opportunity theory and apply it to scientific research.

Melissa S. Anderson RCR Training and Mentoring: Associations with Ethically Questionable Behavior

The aim of this paper is to examine relationships between the extent and types of training and mentoring in ethics that scientists receive and questionable behaviors in which they engage.

This study is part of a larger program of research having a broad, long-term objective of adapting and applying the ethical sensitivity concept to the conflict of interest domain, with the ultimate goal of increasing researchers' sensitivity to conflicts of interest. The objective of this preliminary investigation is to define Conflict of Interest (COI) Sensitivity and test whether it can reliably be assessed. In this study, we provide conceptual and operational definitions of COI Sensitivity, and develop/pilot test stimulus materials and coding procedures for assessing COI sensitivity.

Friday 6:00-6:30**Reception****Friday 7:00-9:00****Dinner & Keynote Address**

Ana Marusic

Trust but Verify: Strengths, Weaknesses, Opportunities and Threats of Scientific Publishing

Saturday 8:00-10:00**Concurrent Track One: The Role of the Individual**

Jason Hill

Validation of Ethical Decision-Making Measures: Internal and External Validity

Ethical decision-making measures are widely applied as the principal dependent variable in studies of research integrity. However, evidence bearing on the internal and external validity of these measures is not available. The intent of the present study was to assess the validity of a new set of ethical decision-making measures.

Melissa Anderson

Scientists' Normative Orientations: Normative Dissonance and Ethically Questionable Behavior

This paper analyzes the normative orientations of scientists, with particular attention to dissonance among their subscription to norms of various kinds, their own behavior, and their perceptions of their colleagues' behavior. It furthermore examines relationships between scientists' normative orientations and their participation in ethically questionable behaviors.

Alison L. Antes

Ethical Decision-Making in Research: Exploring the Influence of Personality

The aim of the present study was to explore the influence of key personality variables on ethical decision-making in research settings. Understanding personality variables provides an essential piece of the framework necessary for effectively predicting ethical behavior and implementing research integrity interventions

Darko Hren

Development of moral reasoning during medical school

To investigate differences in moral reasoning among medical students at different stages of their medical studies.

Saturday 8:00-10:00**Concurrent Track Two: Journals, Authorship and Publication**

Elizabeth Boyd

Conflicts of Interest and Editorial Decision-making: How editors', peer reviewers', and authors' disclosed conflicts affect decisions to publish manuscripts

Little is known about the actual decision-making processes through which journal editors decide to accept or reject submitted manuscripts, how authors', peer reviewers' or editors' personal or financial conflicts of interest are taken into consideration, or how those conflicts impact editors' decisions to accept or reject submitted manuscripts. Our objective was to determine whether, what type, and how conflicts of interest were discussed by journal editors during manuscript evaluation, and how those conflicts figured into editorial decision-making.

Previous studies have shown that medical journals varied in their requirements that authors document informed consent and human subjects review. Less is known about journals' requirements concerning authorship ethics. This study describes variation in ethical requirements in the instructions for authors of a sample of journals publishing clinical trials.

We conducted a large prospective study at three major biomedical journals to identify predictors of publication among submitted manuscripts, evaluate whether publication bias occurs at the editorial level, and assess the quality and added value of peer review.

To investigate how categorization of journal articles by a citation database affects the impact factor, which is calculated as the ratio between the number of citation to all journal items (numerator) and the number of "article" and "review" items (denominator) during a certain time period.

Research misconduct often includes components of unethical authorship and publication practices raising the question of what role scientific societies should play in addressing these issues. In this study, publication and authorship guidelines appearing in scientific societies' ethics codes were reviewed for their coverage of these important areas.

Saturday 8:00-10:00 **Concurrent Track Three: RCR Instruction**

Within scientific and academic communities, a number of research misconduct cases have demonstrated the need for ethics training. A Responsible Conduct of Research (RCR) Training Program was developed to address these concerns among professionals and graduate students. Training effectiveness was assessed through an analysis of quantitative and qualitative training assessments.

This two-phase, mixed method (quantitative/qualitative) study examines practices regarding the responsible conduct of research (RCR) in behavioral health educational programs (psychiatry, social work, psychology, counseling, psychiatric nursing). Specifically, we aim to describe research review and monitoring mechanisms and explore the extent to which RCR is included in curricula.

Research misconduct undermines the scientific enterprise by comprising the integrity of research. There is currently a lack of evidence concerning the environmental factors that promote research integrity. This analysis examines the efficiency of the environmental factors of educational programs addressing record keeping and policies addressing record keeping in promoting research integrity

The purpose of this study is to determine whether teaching RCR along with additional science-specific ethics topics results in a better understanding of the principles of RCR and/or attitudes toward ethical issues in research.

Saturday 10:15-12:15 **Concurrent Track One: The Role of the Individual (Panel Discussion)**

This panel will present four papers from the Motivating Research Integrity Project, a recent study of challenges to research integrity. We conducted interviews with 60 human subjects' researchers, posing 5 dilemma-based vignettes. The overall study aims were to: (1) assess researchers' problem-solving strategies when confronted with ambiguous situations in research; and (2) describe the norms that guide individual research practices. Specific issues will be highlighted in each presentation.

H Linn The Making of a Conflicted Scientist: How Different Structures and Aspects of the Research Process Create Conflict for a Scientist

In this analysis, we examine responses to a specific vignette posing a publication issue involving negative findings and a politically charged climate, as well as the rationales behind these actions. We identified four themes that were central to researcher decision-making in this vignette, and may extend to research conduct more broadly. Specific ethical challenges surrounding publication will also be discussed.

Helene Starks Data Ownership: Preserving reputations and relationships when data get pulled without warning

This paper examines the common responses and rationales for actions taken in a data ownership dilemma. Respondents used a combination of negotiation, self-evaluation, and appealing to higher authorities in the interest of promoting their career, getting credit for their work, and preserving their reputation or relationships. Participants had a heightened sense of power and what's at stake; they would seek all possible avenues to a reasonable compromise, mindful of the costs to relationships and career.

S Fullerton En-gendering Thoughts on Research Integrity: Comparing Male and Female Investigators' Responses to Ethical Dilemmas

Recent research has suggested that, among other factors, gender may influence the degree to which investigators report involvement in research misconduct. In our investigation of defined research dilemmas, rather than misconduct self-report, we observed no strong differences in primary responses to vignettes but did observe gender differences in the rationales offered for the responses, suggesting gender may play a role in addressing research challenges

Kelly Fryer- Stepping Up: Taking Responsibility for Research Integrity

Participants voiced concerns about career and reputation, as well as often competing obligations to science, teams, subjects or society more broadly. In our sample, researchers could acknowledge the competing motivations, but could also work through to creative solutions that would allow them to satisfy their obligations. We close the panel with some suggestions for changes within the culture and climate of research practice that could enhance research integrity.

Saturday 10:15-12:15 **Concurrent Track Two: Journals, Authorship and Publication (Panel Discussion)**

Kirby Lee Ethical Considerations about Journal Peer Review: Ways to Improve Accountability, Responsibility and Research Integrity

In order to function well, the journal peer review system relies on the integrity and accountability of authors, editors and reviewers. This panel discusses various policies and mechanisms to improve transparency, promote fair review, and facilitate data access for peer review. Panel members: Kirby Lee, Lisa Bero, Elizabeth Boyd, and Ana Marusic

Saturday 10:15-12:15 **Concurrent Track Three: RCR Instruction**

This study is final part of research project on prevalence and attitudes towards plagiarism and dishonesty among medical students. The purpose of study is to build basis for education reform and improvement of university policies on scientific integrity and its promotion among future physicians and biomedical scientists in Croatia.

In 2005, SDSU received funding from the Office of Research Integrity to develop a training module for novice/lay research staff to promote an understanding of basic research concepts. The need for this training was prompted by investigators who involve research staff (e.g., community health workers (CHW), college students and clinical staff) to assist in carrying out research protocols. Preliminary data indicate that most CHWs involved in community health interventions have a high school education and have not received formal training in research methods. Likewise, many undergraduate programs are introducing research component in the curriculum and recognize that a basic foundation of research concepts is necessary for students to understand ethical and responsible research practices. If the research design is not understood, the protocol may not be carried out as intended and, subsequently, compromise scientific integrity.

Federal regulators and participant advocates have called for empirical data that can aid universities foster scientific integrity of students and faculty. The field of psychology is an ideal venue to pioneer RCR instruments because of its 50 year history of ethical codes covering the conduct of research, the field's expertise in test construction, and an existing set of psychometrically sound instruments for mentoring and departmental influences on scientific training in general. Drawing upon a sample of 200 psychology graduate students nation-wide, this study reports the development and validation of Internet-based measures of RCR mentoring, RCR departmental climate, students' perceived RCR preparedness.

Identifying untoward effects of participation in research involving deception is essential to informed decision making by Institutional Review Boards (IRB). Deception may be used when participant knowledge of the study purpose, hypotheses or procedures may bias or influence behavior and compromise the validity of results. Deception is more common in social/behavioral sciences when, in order to study attitudes or behavior, participants are deliberately misinformed about the true study purpose. The primary ethical concern is the inability to obtain informed consent which violates a basic tenet of the Belmont Report ^ Respect for Persons.

The purpose of this study was to assess student responses to participation in a social psychology study involving deception. The „parent% study explored reaction to social exclusion. Subjects were randomly assigned to receive feedback that they were either, accident prone, socially undesirable or generally happy. Upon completion of the study and debriefing, thirty-six undergraduates completed a ten-item survey to describe their experience, feelings during participation and after debrief, desire to discuss feelings, value of informed consent, and the utility of deception to achieve the study goals.

Saturday 1:30-3:30**Concurrent Track One: The Role of the Individual**

To describe NIEHS researchers' experience with twenty different behaviors related to the responsible conduct of research pertaining to the work at the NIEHS and elsewhere.

S Murphy The development of ethical decision-making: Early environmental predictors of research integrity

It is commonly held that early career experiences act to influence ethical behavior. One way early career experiences might operate is to influence decisions people make in ethical contexts. The intent of the present study was to examine the influences of career experiences and perceptions of climate on day-to-day ethical decision-making.

V Katavic Research Climate at the University of Zagreb School of Medicine

The aim of the study is to assess the research climate and to try to identify various situations that influence research integrity of junior staff in the setting of our School at the University of Zagreb School of Medicine

Janet Holdsworth Everyday Ethics: How Life Scientists Manage University Policies Governing Research

A largely unacknowledged crisis is emerging as a result of increasing university regulation of life sciences research. This study investigated scientists' perceptions of policies and regulations, examined institutional variations in regulatory climate, and explored how tensions between scientific aims and institutional regulations affect decisions about research agendas.

Saturday 1:30-3:30 **Concurrent Track Two: Journals, Authorship and Publication**

Sheldon Gelman Can multiple authorship reduce scientific misconduct?

This presentation explores the issue of multiple authorship in publication and its impact on scientific misconduct in academia. Academicians are well aware that the pressure to publish can lead to becoming, if not unethical behavior. Multiple authorship and collaborative mentoring may limit cases of plagiarism and data falsification.

Darko Hren Does instruction on authorship criteria influence students' decisions and justifications about authorship dilemmas?

To investigate the effect of instruction on ICMJE authorship criteria on: A) students' decisions regarding ethical dilemmas which involve an authorship problem; B) their justifications of these decisions. Also, to contribute to the theoretical issue of rationalist vs. intuitionist model of moral judgment.

Ana Marusic Quantification of Authors' Contributions and Eligibility for Authorship: Randomized Trial in a General Medical Journal

To analyze if the structure of the contribution disclosure form influences authors' declaration of their contribution to the manuscript and to test if a form with a rating scale would reduce the final proportion of honorary authors in comparison with a binary contribution disclosure form.

Sharon Moss Research Integrity in the American Speech-Language-Hearing Association: Scientific Publication Practices

The purpose of this session is to report findings from the American Speech-Language-Hearing Association's survey of issues related to research integrity and publication practices. ASHA is keenly interested in the importance of research integrity to its members and to readers of its scientific journals. The ASHA survey was funded by the National Institute of Neurological Diseases and Stroke (RO1 NS44534-01S1) to study education practices and scientific publication practices.

Saturday 1:30-3:30 **Concurrent Track Three: Issues in the Design and Conduct of Clinical Trials**

B Barnes Application of Ethical Principles during the Informed Consent Process for Clinical Trials

Despite mandatory education in abstract ethical principles, application of these principles, particularly in investigator-subject communication, remains inadequate. The purpose of this project was to develop an educational strategy to increase the competency of investigators and research coordinators related to the informed consent process for clinical trials. This project was supported by the NIH Human Subjects Research Enhancement Program (2S07 RR18239-02).

Leslie Alexander Piloting the Waters of Research with Indigenous Staff

Research extenders (REs) are research staff indigenous to targeted research populations and therefore effective in working with research subjects. This presentation describes lessons learned from the pilot phase of a study of REs, their experiences and their responses to ethical issues involving human subjects. Data and methodological issues are discussed.

Deb DeBruin Re-thinking Clinical Research Ethics: From Protocol Design to Everyday Practice (Panel)

Research ethics focuses on protocol design and prospective review of clinical trials. Little is known about the everyday work of clinical trials. This presentation will report the results of one of the first empirical studies of moral challenges in this everyday work and discuss the implications for research ethics/integrity.

Saturday 3:45-5:45 **Plenary: Prevalence**

Sandra Titus NIH Investigators' Observations on Misconduct: What do they report they observe on fabrication, falsification and plagiarism?

To describe the incidence and types of misconduct that investigators report that they have observed in the past three years. To examine the implications of these findings.

Barbara Habermann Actual Occurrences of Scientific Misconduct: A National Survey of Research Coordinators

To conduct a national survey of research coordinators (RC) to describe their attitudes and beliefs about scientific misconduct (SM); their perceptions of factors influencing SM; and their actual experiences with SM.

Matthias Kaiser "Can we trust research? – Reports from two empirical studies in Norway.

"Whether or not to trust research can depend on a number of factors. One is whether the scientists carrying out the research engage in scientific misconduct or other ethically problematic behaviour. We carried out an empirical study in 1996/97 where we asked university scientists from natural science and social science / humanities about scientific misconduct. We did not only inquire about their direct or indirect knowledge of such behaviour, but we also asked them to report problematic behaviour they themselves have engaged in. The results suffered from a low response rate, but among those responding we detected an amazingly high occurrence of self-reported irregular behaviour.

At about the same time the Norwegian Parliament asked whether one still can trust science and the research carried out under the name of science, when apparently large parts of that research is directly financed by parties with sectorial interests, be they private or governmental parties. After several years of controversy about this assignment, the empirical research was finally conducted and published in 2003. The interesting results were in part from the qualitative section of the study, and in part from the quantitative section, showing among others a significant numbers of cases where the funders tried to control either the methodological aspects of the research or tried to stop publication of the results. "

Joan Sieber A Collegial Defense Against Irresponsible Science

Cases of whistleblowing have attracted publicity, but little is known about behind-the-scenes collegial interventions when invalid or inappropriate research is observed. This project examines such interventions, strategies employed under varying circumstances (e.g., status differentials) and the success or failure of such strategies. An online casebook and manual will be developed successfully and unsuccessfully.

Saturday 6:00 ff **Dinner on own or with groups organized earlier in the day**

Sunday 8:30-10:00**Concurrent: Climate**

Timothy Atkinson Power, Integrity and the Institutional Construction of Norms in University Research Administration

The goal of this study was to gain a better understanding of research administrators' perceptions of normative structures present in university research administration. The existence of a stable norm structure should assist ethical behavior. Institutional theory informed analyses of the research environment from both micro and macro analytical levels.

Karen Louis Entrepreneurial Professors and Secrecy in Science: Variations and Impacts

University relationships with industry have been a hot topic for nearly two decades. There are concerns that increasing faculty involvement in research commercialization will affect the exchange of ideas in the scientific community. This paper investigates four different types of faculty entrepreneurship and finds that each type is characterized by different behavior.

James Vander Putten Organizational Culture for Research Integrity in Academic Health Centers

This quantitative pilot study tested a brief survey to investigate faculty perceptions of academic organizational culture and climate characteristics that promote research integrity. Faculty at one academic health center (n=47) were surveyed, and the results provide initial insights into important dimensions of organizational culture that can promote research integrity.

Sunday 8:30-10:00**Concurrent: Moral Considerations**

Elizabeth Ripley Paying Research Participants: Attitudes and Practices of Investigators

The ethics of paying research participants has been widely debated; however, there is little empirical data to evaluate current practices and opinions of investigators. This study aimed to evaluate current practices of investigators including how, why, and how much they pay research participants.

Thomas May Deception, Cheating and the Normative Legitimacy of IRBs

To examine how recent reports of IRB cheating and deception might call into question the normative legitimacy of IRBs.

Janet Malek To Tell or Not to Tell? The Ethical Dilemma of the Would-be Whistleblower

In all but the most egregious cases, the question of whether a would-be whistleblower should report suspected research misconduct is difficult to answer with certainty. The goal of this project was to develop a framework to help determine when an individual has a moral obligation to report suspected research misconduct.

Sunday 8:30-10:00**Concurrent: Questionable Research Practices**

Brenda Jeffers Research Environments and the Research Report Card

The objective is to present a method for public reporting of research integrity practices within research environments. An internal control model is used to identify and assess key environmental research integrity practices and a sample research report card is formulated.

Nanyan Cao Questionable Research Practices (QRP): A Difficult But Important Research Area

In her RCR teaching, the author noticed that most students are unambiguously against research misconduct, yet they do not pay enough attention to QRP. Moreover, quite a few of them agree to, or even yearn for QRP. Therefore, the author is engaged in research on college students' attitude to QRP, causes and harms of QRP prevailing in research community, and methods to prevent QRP.

Although questionable research practices and research misconduct have been widely discussed in the research literature, no known measures exist to assess questionable research practices (QRP). The current measure was developed to measure QRP and is theoretically based on ORI's 9 areas of responsible conduct of research.

Sunday 10:15-12:15**Plenary: Impacts and Policy Implications**

Dennis M Gorman

Reanalysis of Data from an Evaluation of the DARE Program using Questionable Data Analysis and Presentation Practices

In order to assess whether use of irregular and questionable data analysis and presentation practices result in significant overestimation of program effects, we will re-analyze data from a large-scale evaluation of the DARE program using questionable practices employed in evaluations of other widely used drug and violence prevention programs.

Ambuj Kumar

Unrealistic expectations of treatment effects may hamper advancements in medicine: a review of randomized trials conducted by 3 NCI cooperative groups

Inconclusive findings from randomized clinical (RCT) trials represent waste of precious resources and ethical breach of contracts with patients who expect that definitive answers will help future patients. Our objective was to find out how often and why results from RCTs are inconclusive

Chuck Lidz

Competing Commitments in Clinical Trials Research

Clinical trials researchers face competing commitments between the best interests of their patients and gathering valid data. Many commentators are concerned that subjects do not get good treatment. Almost ignored has been whether the clinical concerns of researchers have undercut good research practices.

Heloisa P. Soares

Lack of reporting harms in the NCI sponsored phase III hematological malignancies trials leads to outcomes reporting bias.

To make informed decisions, patients and physicians need accurate information both on treatment benefits and harms. However, reports of trials typically focus on description of benefits only. Therefore, our objective is to assess the quality of reporting of treatment-related mortality (TRM) and morbidity (TRMorb) in cancer.

Sunday 12:15-12:30**Closing Discussion and Comments**